PATENT COOPERATION TREATY

PCT

Appl. No. 10/594,436
Doc. Ref. NPL2

270

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference E0006VP16PCT	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/JP2006/319147	International filing date *(day/month/year)* 27 September 2006 (27.09.2006)	Priority date *(day/month/year)* 29 September 2005 (29.09.2005)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant Eisai R & D Management Co., Ltd.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 01 April 2008 (01.04.2008)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Yoshiko Kuwahara e-mail: pt07.pct@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

TRANSLATION

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

	Date of mailing *(day/month/year)*
Applicant's or agent's file reference E0006VP16PCT	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/JP2006/319147	27.09.2006	29.09.2005

International Patent Classification (IPC) or both national classification and IPC

Applicant
Eisai R & D Management Co., Ltd.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I — Basis of the opinion
- ☐ Box No. II — Priority
- ☐ Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV — Lack of unity of invention
- ☒ Box No. V — Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI — Certain documents cited
- ☐ Box No. VII — Certain defects in the international application
- ☒ Box No. VIII — Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP	Date of completion of this opinion	Authorized officer
Facsimile No.		Telephone No.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2006/319147

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

☒ the international application in the language in which it was filed

☐ the translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rule 12.3(a) and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ on paper

☐ in electronic form

c. time of filing/furnishing

☐ contained in the international application as filed

☐ filed together with the international application in electronic form

☐ furnished subsequently to this Authority for the purposes of search

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-15	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-15	NO
Industrial applicability (IA)	Claims	1-15	YES
	Claims		NO

2. Citations and explanations:

Document 1: JP, 2003-522141, A (EURAND PHARM LTD.), 22 July, 2003 (22.07.03)
Document 2: JP, 2001-270827, A (EISAI CO., LTD.), 2 October, 2001 (02.10.01)
Document 3: JP, 2000-355540, A (EISAI CO., LTD.), 26 December, 2000 (26.12.00)
Document 4: JP, 2002-529397, A (ASTRAZENECA AB.), 10 September, 2002 (10.09.02)
Document 5: JP, 2003-171277, A (LEDERLE JAPAN LTD.), 17 June, 2003 (17.06.03)

Inventive step
Claims 1-6 and 8-15

Document 1 describes a pulse elution preparation in which (1) a core having a medicine is covered with a first layer containing a methacrylic acid copolymer which is an enteric polymer, and (2) the said enteric coating layer is further covered with a second layer containing ethyl cellulose which is a water-insoluble polymer and the said methacrylic acid copolymer. Furthermore, in the said preparation, releasing of the medicine is started after a predetermined time has passed (examples 1, 2, and 4).

In addition, document 1 also describes that the said pulse elution preparation contains an intermediate coating layer between the said core and the said first layer (examples 1 and 2), and further contains an intermediate coating layer between the said first layer and second layer (example 4).

In the comparison between the subject matter of claim 1 of the present application and the invention described in document 1, a core in the former includes a disintegrating agent, though the latter do not specify it unlike the former, other points are matched.

Here, a preparation that generally requires pulse-type elution characteristics is expected to immediately release a medicine after moisture content is penetrated inside the preparation, after a predetermined time has passed. It is considered to have been widely known to a person skilled in the art that using a disintegrating agent is effective for promoting the discharge of an active ingredient, in the field of oral preparations before the priority date of the present application. So, a person skilled in the art could have easily conceived of mixing a disintegrating agent into a core, in the pulse elution preparation described in document 1.

Furthermore, document 1 describes that omeprazole can be selected as a medicine (claim 6). As described in documents 2-4, when a benzimidazole-based compound, such as omeprazole, which is unstable to acids is mixed, adding alkaline substances as a stabilizing agent of the said compound is not requited any special inventive idea.

In addition, a person skilled in the art could have, as required, arrived at selecting each component or a production method among those well-known, or applying a general dosage form such as a complex discharge type which uses a fast-acting component and a continuous component together.

Furthermore, it is not considered that the subject matters of claims 1-6 and 8-15 of the

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

present application exhibit an especially prominent effect that a person skilled in the art could not have predicted from documents 1-4 and the well-known techniques.

Claims 1-5 and 7-15

Document 5 describes that a core containing a medicine is covered with an outer layer containing crystalline cellulose which is a water-insoluble polymer and a hydroxypropylcellulose which is a water-soluble polymer, thereby to obtain a medicine time-controlling type solid preparation having a pulse type release characteristic.

Therefore, in expectation of similar performance of the coating layer having the water-insoluble polymer and the enteric polymer described in document 1, a person skilled in the art could have easily conceived of applying the outer layer described in document 5, replacing of the second layer of the pulse elution preparation described in document 1.

The above examination applies to other points.

Furthermore, since there is no example using the water-soluble polymer in the specification of the present application, it is not considered that the subject matters of claims 1-5 and 7-15 of the present application exhibit an especially prominent effect that a person skilled in the art could have not predicted from documents 1-5 and the well-known techniques, by changing the outer layer.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 2 and 3

Claims 2 and 3 describe "an inactive intermediate coating layer". However, the kind of layers contained in the said coating layer is unclear from the description of "inactive".

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Int.Cl.

A61K47/32(2006.01)i, A61K9/14(2006.01)i,
A61K9/16(2006.01)i, A61K9/20(2006.01)i,
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A61K47/46(2006.01)i